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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,741	10/17/2001	Matthew T. Scholz	54402US028	7855

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05/09/2002

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EXAMINER

EGAN, BRIAN P

ART UNIT

PAPER NUMBER

1772

6

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-4

Office Action Summary	Application No.	Applicant(s)	
	09/982,741	SCHOLZ ET AL.	
	Examiner	Art Unit	
	Brian P. Egan	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The abstract is objected to. Lines 7-9 read, "Also disclosed are friction control articles having a coefficient of friction when dry along at least a portion of the first surface is at least 0.6." The sentence is unclear. Examiner suggests replacing "is at least 0.6" with "of at least 0.6" to facilitate clarity. Proper clarification and/or correction are required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-7, and 24 are rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention. The use of the "Stainless Steel Coefficient of Friction" is unclear. The applicant refers to the static coefficient of friction throughout the disclosure and then only refers to the Stainless Steel Coefficient of Friction in Example 11 of the specification. It is unclear whether the Stainless Steel Coefficient of Friction is equivalent to the static coefficient of friction. Furthermore, the applicant suggests that the test performed was equivalent to the "Stainless Steel Kinetic Coefficient of Friction Test" as described in U.S. Patent No. 4,667,661 to Scholz et al. The applicant, however, changed the test by having the "flat side of the sled against the sample." Therefore, it is unclear whether this change in testing procedure yields an acceptable "Stainless Steel Kinetic Coefficient of Friction" value and whether it is proper to refer to such values as the Stainless Steel Coefficient of Friction when the test method was not entirely adhered to. Proper clarification and/or correction is required.

4. Claims 4-7, and 24 are further rejected under 35 U.S.C. 112, second paragraph, for a lack of antecedent basis for “*the* Stainless Steel Coefficient of Friction.” Proper correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1-8, 20-22, and 24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cejka et al. (#6,106,922).

Cejka et al. disclose a stemmed web that can be used in virtually any application as any other stemmed web (Col. 6, lines 35-36) comprising a backing layer having a first surface and a second surface (Col. 1, lines 63-64), where projecting from the first surface of the backing layer is an array of stems (Col. 1, lines 64-67) – the stems comprising at least a portion of thermoplastic elastomeric material on the exterior surface of the stems (Col. 2, lines 3-5). The stems are generally upstanding (See Figs. 1-8). The second surface of the backing layer may also comprise an array of stems protruding from the surface (See Fig. 8). The density of the stems is at least 15.5 stems/cm² (“densities ranging from 12-465 stems per square centimeter”; Col. 5, lines 54-55) wherein the aspect ratio of the stems on the first surface is at least 1.25 (stem

Art Unit: 1772

height : stem diameter) (See Examples section; Col. 6, lines 46-48; $15/1.25 = 12$). The elastomeric materials are selected from polypropylene, polyethylene, polystyrene, polycarbonate, polymethyl methacrylate, ethylene vinyl acetate copolymers, acrylate modified ethylene vinyl acetate polymers, ethylene acrylic acid copolymers, synthetic rubber, styrene block copolymers containing isoprene, butadiene, or ethylene (butylenes) blocks, metallocene-catalyzed polyolefins, polyurethanes or poly diorganosiloxanes, pressure-sensitive adhesives, and hot-melt adhesives (Col. 3, line 58 to Col. 4, line 5). Although Cejka et al. do not explicitly state the material property of stainless steel coefficient of friction, the surface friction of 0.6 when dry and surface friction when wet being within 20% of this value is inherently met since the friction factor is contingent upon the material composition of the stems – a composition that is anticipated by Cejka et al. Furthermore, Cejka et al. state that performance properties of the stemmed web can be modified based on the selection of materials (Col. 3, lines 33-36).

7. Claims 1-7, 9-10, 19-20, 22, and 24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Crawley et al. (#5,948,707).

Crawley et al. disclose a medical drape (Col. 5, line 6) comprising a backing layer having a first surface and a second surface (Fig. 1, #12), where projecting from the first surface of the backing layer is an array of stems (Fig. 1, #15; Col. 4, lines 5-13), wherein at least a portion of the exterior surface of the stems comprises a thermoplastic elastomeric material (Col. 8, lines 15-17). The stems of the drape are generally upstanding and have a stainless steel static coefficient of friction of at least 0.6 (Col. 3, lines 49-57). Crawley et al. do not explicitly state that the stems have a coefficient of friction within 20% of 0.6 when wet although this limitation is inherently met given that the material limitations have been met by the reference – thereby inherently

Art Unit: 1772

proving the material property of friction. The medical drape further comprises a second backing layer adjacent to the second surface of the first backing layer (Fig. 1, #16) where projecting from the second backing layer is a second array of stems, the second array of stems comprising an elastomeric material (Col. 8, lines 44-47). The density of the stems on the first surface of the backing layer is at least 15.5 stems/cm² (See Example 2; given a diameter of 0.53mm and the fact that the stems can be distributed to cover 5-95% of the surface area (Col. 7, lines 11-15), 15.5 stems/cm² would only cover 3.47% of the surface area (radius = 2.65mm, $\pi \times 2.65^2 \times 15.5$ stems = 3.417mm² = 0.03417cm², 0.03417 x 100 = 3.417% of surface area covered with 15.5 stems) therefore, to cover at least 5% of the surface area, there will have to be more than 15.5 stems/cm²). The elastomeric material comprises silicon rubber (Col. 8, lines 17-19). Although Crawley et al. do not explicitly state that the medical drape comprises micro-channels between the stems along at least a portion of the exterior of the first surface of the backing layer, Crawley et al. state that the backing is water vapor permeable, thereby demonstrating the existence of micro-channels within the material (Col. 3, lines 64-65).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawley et al. ('707) in view of Lind et al. (#4,204,532).

Crawley et al. teach a medical drape structure as shown above. Crawley et al. fail to teach a reinforcing layer disposed between the first and second backing layers.

Lind et al., however, teach a surgical drape with a non-skid fenestration material layer (See Abstract). Lind et al. teach a fenestration material with a scrim reinforcement that can be either woven or non-woven. Lind et al. provide the fenestration structure for the purpose of improving instrument retaining and non-skid characteristics while eliminating the undesirable absorbency characteristics of prior art (Col. 1, lines 42-47) as well as to provide a material that can withstand sterilization techniques utilized for materials having medical applications (Col. 4, lines 51-54). It would have been obvious through routine experimentation to one of ordinary skill in the art at the time applicant's invention was made to have used a reinforcement fenestration structure between the base material layers of a medical drape structure for the purpose of improving the instrument retaining, non-skid, and absorbency characteristics of the drape as well as to provide a material that can withstand the sterilization techniques utilized for materials having medical applications as taught by Lind et al.

Therefore, it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have modified Crawley et al. to include a reinforcement fenestration structure between the first and second base layers as taught by Lind et al. in order to improve the instrument retaining, non-skid, and absorbency characteristics of the drape as well as to provide a material that can withstand the sterilization techniques utilized for materials having medical applications.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crawley et al. ('707) in view of Chen (#3,972,328).

Art Unit: 1772

Crawley et al. teach a medical drape as described above. Crawley et al. fail to teach the addition of an antioxidant to the elastomeric material of the drape.

Chen, however, teaches a surgical bandage that comprises an antioxidant (butylated hydroxytoluene or butylated hydroxyanisole) for the purpose of prolonging the shelf life of the bandage (Col. 2, lines 3-7 and lines 44-48). It would have been obvious through routine experimentation to one of ordinary skill in the art at the time applicant's invention was made to have used an antioxidant along with the elastomeric material of a medical drape for the purpose of prolonging the shelf life of the drape as taught by Chen.


Therefore, it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have modified Crawley et al. to include antioxidants in the elastomeric material of the medical drape as taught by Chen in order to prolong the shelf life of the drape.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian P. Egan whose telephone number is 703-305-3144. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y. Pyon can be reached on 703-308-4251. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772 5/3/02

Application/Control Number: 09/982,741
Art Unit: 1772

Page 8

BPE
May 3, 2002